

6111 Broken Sound Parkway NW Boca Raton, FL 33487-3693 (561) 241-9400 Fax (561) 995-5188

11892 '99 APR 20 P2:U4

March 31, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204 14 5 99 J

Dear Sirs: -

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

Ginkgo Biloba: For mental alertness. Ginkgo Biloba promotes healthy brain function, memory and mental alertness by increasing blood circulation to the brain. It also provides antioxidant protection against cellular damage. To further promote healthy brain function and memory, take this product with Sundown Memory Care™ and Sundown CoQ-10.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborak Skur Jonh

Deborah Shur Trinker Vice President of Regulatory Affairs and Assistant General Counsel

Enclosure